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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,383	02/15/2001	John C. Voellmicke	DEP0468	3939

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EXAMINER

LEWIS, RALPH A

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,383

Applicant(s)

VOELLMICKE ET AL.

Examiner

Ralph A. Lewis

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9, 33, 34, 40, 44-62, 79-83 and 100 is/are pending in the application.
- 4a) Of the above claim(s) 8, 42, 43 and 55-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7, 9, 12-15, 33, 34, 40, 44-53, 59-62, 79-83 and 100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/26/2003</u> | 6) <input type="checkbox"/> Other: _____ |

Informality in Claim Identifiers

The response of 09/03/2002 clearly cancels claims 85-99, however, the current response lists the majority of these claims as being "withdrawn." It is improper to reinstate a cancelled claim.

Petition to Delete Inventors Approved

In view of the papers filed 26 June 2003, the inventorship in this nonprovisional application has been changed by the deletion of Nolene Harris, Neil Watkins and Rick Kowalski.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Rejections based on Prior Art

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 9, 12-15, 40, 44-53 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tolson (6,217,581 B1) in view of Scales (4,405,249) and Jaques (1,894,274).

Tolson discloses a bone cement injection device for injecting bone cement under high pressure into a bone cavity that includes a levered "high pressure, manually operated, hydraulic action gun 20 widely used for greasing automobiles" (column 2, lines 43-45). Tolson does not explicitly disclose that the injection device is sterile, however, one of ordinary skill in the art would readily recognize that surgical devices are routinely sterilized so as to help prevent infections. Scales (column 3, lines 3-7; column 4, lines 64-68) teaches that such bone cement injection devices are sterile/sterilized to prevent infection. To have sterilized the Tolson injection device 20 so as to help prevent infections would have been routine and obvious to one of ordinary skill in the art. Additionally, Tolson doesn't explicitly disclose a two chambered device with a reservoir and an injection chamber, but from the Figures illustrating the outside of the device it certainly appears to have such features. Moreover, Jacques is cited as disclosing a typical prior art levered automotive lubricating gun having a reservoir chamber 1 with exit opening 45, injection chamber 50, entry opening 44, and impermeable first piston 49. To have used a sterilized prior art lubricating gun as the high pressure injection gun 20 disclosed by Tolson would have been obvious to one of ordinary skill in the art in light of Tolson's Figures showing a very similar gun and disclosure that the gun may be those typically found in the automotive lubricating art.

In regard to the limitation of claim 5 that the first piston have a center point which with the exit opening define a flow path of less than 45 degrees (or substantially linear in claim 6). It is noted that the two points in the Jaques reference make for a straight line. To the extent that applicant is trying to claim that the flow path through the exit is linear with respect to the axis of the injection chamber, it is noted that Tolson clearly shows such an arrangement. Merely repositioning the outlet nozzle 47, 48 of the Jacques injection tool so that it is in alignment with the longitudinal axis of the injection chamber as it is illustrated in the Tolson reference would have been obvious to one of ordinary skill in the art. In regard to claims 9 and 40, the specific volumes claimed would have been obvious to one of ordinary skill in the art as a matter of routine design. In regard to claim 50, note compression spring 34 of Jacques.

Claims 5, 6, 9, 12-15, 33, 34, 40, 44-53, 59-62, 79-81 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tolson (6,217,581 B1) in view of Scales (4,405,249) and Stamper (4,168,787).

Tolson discloses a bone cement injection device for injecting bone cement under high pressure into a bone cavity that includes a levered "high pressure, manually operated, hydraulic action gun 20 widely used for greasing automobiles" (column 2, lines 43-45). Tolson does not explicitly disclose that the injection device is sterile, however, one of ordinary skill in the art would readily recognize that surgical devices are routinely sterilized so as to help prevent infections. Scales (column 3, lines 3-7; column 4, lines 64-68) teaches that such bone cement injection devices are sterile/sterilized to

prevent infection. To have sterilized the Tolson injection device 20 so as to help prevent infections would have been routine and obvious to one of ordinary skill in the art. Additionally, Tolson doesn't explicitly disclose a two chambered device with a reservoir and an injection chamber, but from the Figures illustrating the outside of the device it certainly appears to have such features. Moreover, Stamper is cited as disclosing a typical prior art levered automotive lubricating gun having a reservoir chamber 21 with exit opening 42, injection chamber 23, entry opening 44, and impermeable first piston 49. To have used a sterilized Stamper prior art lubricating gun as the high pressure injection gun 20 disclosed by Tolson would have been obvious to one of ordinary skill in the art in light of Tolson's Figures showing a very similar gun and disclosure that the gun may be those typically found in the automotive lubricating art.

In regard to the limitation of claim 5 that the first piston have a center point which with the exit opening define a flow path of less than 45 degrees (or substantially linear in claim 6). It is noted that the two points in the Stamper reference make for a straight line. To the extent that applicant is trying to claim that the flow path through the exit is linear with respect to the axis of the injection chamber, it is noted that Tolson clearly shows such an arrangement. Merely repositioning the outlet nozzle 47, 48 of the Stamper injection tool so that it is in alignment with the longitudinal axis of the injection chamber as it is illustrated in the Tolson reference would have been obvious to one of ordinary skill in the art. In regard to claims 9 and 40, the specific volumes claimed would have been obvious to one of ordinary skill in the art as a matter of routine design. In regard to claim 33 note check valve 48 which could be manually operated if one

desired such. In regard to claim 34, to have substituted one common prior art check valve for another would have been obvious to the ordinarily skilled artisan

Claims 7, 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tolson (6,217,581 B1) in view of Scales (4,405,249) and Jaques (1,894,274) as applied above with respect to claim and in further view of Phillips et al (4,717,383), Draenert (4,671,263) and Hauke et al (5,551,778).

The Jaques high pressure injector lacks the claimed o-ring on first piston 49. O-rings are conventional on the pistons of high pressure injectors as evidenced by Phillips et al (note piston 12 with o-rings), Draenert (Figure 3, o-rings 52 on piston 50) and Hauke et al (Figure 7, piston 12 with o-ring) to improve the seal between the piston and the chamber. To have provided the Jaques piston 49 with an o-ring to improve the seal with the chamber would have been obvious to one of ordinary skill in the art.

Allowable Subject Matter

Claim 54 is objected to as being dependent on a rejected base claim but would be allowable if rewritten in independent form to include all of the limitations of the claims from which it depends..

Action Made Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Prior Art

Applicant's information disclosure statement of June 26, 2003 has been considered and an initialed copy enclosed herewith.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (703) 872-9306. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Kevin Shaver, can be reached at (571) 272-4720.

R.Lewis
May 2, 2005


Ralph A. Lewis
Primary Examiner
AU 3732